

**REMARKS:**

Reconsideration of the rejections is respectfully requested.

The status of the claims is as follows:

<b>Amended:</b>	None
<b>Cancelled:</b>	None
<b>New:</b>	None
<b>Pending:</b>	38-41
<b>Allowed:</b>	None

The current application teaches methods of accurately depositing an active on discrete areas of a substrate, and thereafter sealing a cover around, but not on, the deposited active. As claimed, the deposition can be such that deposit amount “does not vary from a predetermined target amount by more than 5 weight per cent.”

The primary citation in the Office Action, Mlodozeniec, US 4,332,789, presents in its enabling disclosure an electrostatic deposition of charged pharmaceutical onto a moving web. The web is continuously fed along a charged metal surface, and moves through a chamber containing a cloud of charged particles. See Fig. 2 and 17:30-7. The amount of dosage is regulated by the feed rate of the powder. 15:34-41. This method is designed “to provide a uniformity of flow in order to enable exact and uniform deposition of the active ingredient on the web.” 10:66-8. The entirety of Mlodozeniec’s concrete teachings is about *uniformly coating* the web. See further, for example, 15:64-16:4.

With these methods, Mlodozeniec asserts useful dosing uniformity. When Mlodozeniec teaches laminating multiple layers, he teaches laminating a drug-coated web. When teaching laminating the edges of a web, nothing indicates that the edges not be drug-coated, as in all other concrete teachings of Mlodozeniec. Thus, according to Mlodozeniec:

It is readily apparent from the foregoing disclosure that such a laminate sealed only at the periphery possesses a superior rate of release of medicament than a similar stack of webs which has been totally laminated.

One can discern from the above quotation that in most embodiments all of the drug-coated web is laminated, and thus releases more slowly. In the one edge laminate embodiment, release is faster because the drug-coated laminate is not *totally* laminated, i.e., it is partially laminated.

In one prophetic section, Mlodozeniec speculates, without enabling disclosure, that one might “spot” deposit drug. 26:39-59. Regardless of whether the Office cares to accept what appears self-evident, i.e., that this disclosure is not enabling, it cannot be credibly asserted that it is enabling for depositions that do “not vary from a predetermined target amount by more than 5 weight per cent.” As Mlodozeniec makes clear (e.g., 16:25-32), deposition accuracy is difficult to achieve. Mlodozeniec teaches achieving such accuracy with *uniform* depositions. It cannot be credibly asserted that saying the words “spot deposition” without teaching how to spot deposit discloses or enables *accurate* spot deposition. Mlodozeniec essentially admits this shortcoming at 26:48-54 (emphasis added):

In view of considerations of manufacturing equipment and the need to maintain the integrity of the deposition coating for on-line testing, it is preferred to load active substance continuously onto the web in sufficient amount *so that the unitizing operation produces dosage forms containing a therapeutically efficacious dosage.*

Applicant teaches and claims accurate spot depositions.

Applicant also teaches and claims accurate depositions enclosed by bonds that *surround* the deposition. Mlodozeniec, if one accepted for the sake of argument that it taught such surrounded depositions, does not teach the claimed accuracy in the context of “spot depositions.”

Accordingly, Applicant respectfully submits that the rejection should be withdrawn.

**Conclusion**

In light of these remarks, it is respectfully submitted that the reply should be entered, the rejections should be withdrawn, and that the application is in condition for allowance.<sup>2</sup>

Respectfully submitted,



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<sup>2</sup> **FEE DEFICIENCY**

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